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3

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,143	08/09/2001	Robert B. Schock	DATA_53_CIP	3516

7590 02/26/2003
Datascope Corp.
14 Philips Parkway
Montvale, NJ 07645

EXAMINER

PATEL, NIHIR B

ART UNIT PAPER NUMBER

3743

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/925,143

Applicant(s)

SCHOCK ET AL.

Examiner

Nihir Patel

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 9, 10, and 11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the stylet is an integral part of the catheter) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).
2. Applicant's arguments filed on December 11, 2002 have been fully considered but they are not persuasive. The applicant argues that nowhere in Andrews is there any discussion of a stylet connected to the balloon catheter that is more flexible towards its distal end. The examiner disagrees. Andrews clearly states that the distal end portion of the stylet wire is significantly reduced in diameter to form a floppy J tip. Since the diameter is reduced significantly at the distal end portion of the stylet wire, it is more flexible at the distal end than the proximal end.
3. Amended claims 5 and 7 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claim 5 refers to a non-elected species (figure 6). Claim 7 refers to a non-elected species 7A, 7B, and 7C.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 5 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Andrews et al. U.S.

Patent No. 5,865,721. Andrews discloses a intra-aortic balloon catheters that comprises a balloon membrane (18), a tube (12 and 14), a tip (20), and a stylet (28), the balloon membrane, tube, and stylet each having proximal and distal ends, the distal end of the tube is connected to the proximal end of the balloon membrane (18), the tip (20) is connected to the distal end of the balloon membrane (18), the distal end of the stylet (28) is connected to the tip (20), the proximal end of the stylet is connected to the distal end of the tube (12 and 14), the stylet (28) being more flexible towards the distal end than the proximal end. Refer to figures 1 through 9 and columns 5,6 and 7.

Referring to claim 4, Andrews discloses a reinforcement ring 94 having an inner surface, the reinforcement ring being disposed within the distal end of the tube 12, the proximal end of the stylet 28 being fixed to the inner surface of the ring 94 (See figures 6, 7, 7A, and 7B).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andrews et al. U.S. Patent No. 5,865,721 in view of Valley et al. U.S. Patent No. 5,795,325.

Referring to claim 9, Andrews discloses the applicant's invention as claimed with the exception of providing a fiberoptic sensor and a fiberoptic fiber, the fiberoptic sensor being fixed to the balloon catheter, the fiberoptic fiber extending from the sensor through a space defined by the balloon membrane and through a gas shuttle lumen defined by the tube, the fiber being secured to the stylet.

Valley discloses methods and apparatus for anchoring an occluding member that does provide a fiberoptic sensor and a fiberoptic fiber, the fiberoptic sensor being fixed to the balloon catheter, the fiberoptic fiber extending from the sensor through a space defined by the balloon membrane and through a gas shuttle lumen defined by the tube, the fiber being secured to the stylet. Therefore it would be obvious to modify Andrews's invention by providing a fiberoptic sensor and a fiberoptic fiber, the fiberoptic sensor being fixed to the balloon catheter, the fiberoptic fiber extending from the sensor through a space defined by the balloon membrane and

Art Unit: 3743

through a gas shuttle lumen defined by the tube, the fiber being secured to the stylet in order to obtain accurate results.

Referring to claim 10, Andrews discloses the applicant's invention as claimed with the exception of providing a fiberoptic sensor, a fiberoptic fiber and a thin walled tube disposed over the stylet, the fiberoptic sensor being fixed to the balloon catheter, the fiberoptic fiber extending from the sensor through a space defined by the balloon membrane and through a gas shuttle lumen defined by the tube, the fiberoptic fiber being sandwiched between the stylet and the thin walled tube disposed over the stylet.

Valley discloses methods and apparatus for anchoring an occluding member that does provide a fiberoptic sensor, a fiberoptic fiber and a thin walled tube disposed over the stylet, the fiberoptic sensor being fixed to the balloon catheter, the fiberoptic fiber extending from the sensor through a space defined by the balloon membrane and through a gas shuttle lumen defined by the tube, the fiberoptic fiber being sandwiched between the stylet and the thin walled tube disposed over the stylet. Therefore it would be obvious to modify Andrews's invention by providing a fiberoptic sensor, a fiberoptic fiber and a thin walled tube disposed over the stylet, the fiberoptic sensor being fixed to the balloon catheter, the fiberoptic fiber extending from the sensor through a space defined by the balloon membrane and through a gas shuttle lumen defined by the tube, the fiberoptic fiber being sandwiched between the stylet and the thin walled tube disposed over the stylet in order to obtain accurate results.

Referring to claim 11, Andrews discloses the applicant's invention as claimed with the exception of providing a fiberoptic sensor and a fiberoptic fiber, the fiberoptic sensor being fixed to the balloon catheter, the fiberoptic fiber extending from the sensor through a space defined by

Art Unit: 3743

the balloon membrane and through a gas shuttle lumen defined by the tube, the fiber being embedded in the stylet.

Valley discloses methods and apparatus for anchoring an occluding member that does provide a fiberoptic sensor and a fiberoptic fiber, the fiberoptic sensor being fixed to the balloon catheter, the fiberoptic fiber extending from the sensor through a space defined by the balloon membrane and through a gas shuttle lumen defined by the tube, the fiber being embedded in the stylet. Therefore it would be obvious to modify Andrews's invention by providing a fiberoptic sensor and a fiberoptic fiber, the fiberoptic sensor being fixed to the balloon catheter, the fiberoptic fiber extending from the sensor through a space defined by the balloon membrane and through a gas shuttle lumen defined by the tube, the fiber being embedded in the stylet in order to obtain accurate results.

Conclusion

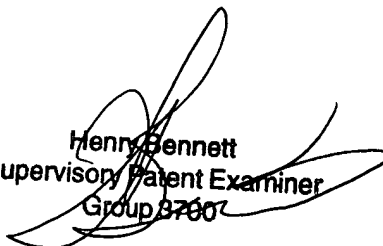
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 3743

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Nihir Patel whose telephone number is (703) 306-3463. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm. If attempts to reach the examiner by telephone are unsuccessful the examiner supervisor Henry Bennett can be reached at (703) 308-0101.

NP
February 10, 2003


Henry Bennett
Supervisory Patent Examiner
Group 8700